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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,514	01/16/2004	Russell Baumann	034827-0705	7027
30542	7590	08/29/2006	EXAMINER	
FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278				LI, BAO Q
ART UNIT		PAPER NUMBER		
		1648		

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,514	BAUMANN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 is/are rejected.
- 7) Claim(s) 2-6 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>8/15/2006</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>H16/2006</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-6 in the reply filed on 06/30/2006 in the scope of SEQ ID NI: 4-5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Urdea et al. (a) (US patent 5,681,691A) or (b) (US Patent No. 5,635,352A).

4. Urdea et al. in (a) or (b) teach a short polynucleotide of SEQ ID NO; 15 that can be used for detecting HCV, wherein the polynucleotide comprising the claimed polynucleotide with 100% identity and it is labeled during the assay (Column 17-19). Therefore, the claims 1-2 are anticipated by the cited reference (a) or (b).

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gene bank accession No. AF 059603 first submitted on April 15, 1998 by Laboratory Shanghai Institute of Biochemistry, Chinese Academy of Science.

6. Laboratory Shanghai Institute of Biochemistry, Chinese Academy of Science discloses a polynucleotide comprising the claimed polynucleotide with 100% homology. Therefore, the claimed polynucleotide is anticipated by the cited reference.

7. Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Michinori et al. (JP 103899-A/1).

8. Michinori et al. disclose a probe of SEQ ID NO: 1 having 37 nuclei acids in that the nucleic acids residues 10-33 is 100% identity to the claimed probe of SEQ ID NO 3. The said

probe is also used for detection of HCV RNA suitable for a fluorescence dye labeling (see line7 on page 10). Therefore, the claims 1-3 are anticipated by the cited reference.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michinori et al. (JP 103899-A/1), Kawai et al. (Journal of Medical Virology 1999, Vol.58, pp. 121-126) and Lee et al. (US Patent NO. 6,316,610B2)..

11. Claimed invention is drawn to short polynucleotides used for detecting HCV, wherein double fluorescent dyes used for labeling probe are VIC and TAMRA.

12. Kawai et al. discloses a similar method of TaqMan for detecting HCV. The method comprises IN HCV control that is an HCV RNA transcribed from pGEM3Zf(+) plasmid DNA by using T7 RNA polymerase (see section of preparation of control HCV RNA). Kawai et al. also teach the HCV specific probe is labeled with dual fluorophores of FAM at the 5' and TAMRA at the 3' (See lines 1-3 on 2nd paragraph of page 122).

13. Regarding to the VIC fluorescent dye, Lee et al. disclose method for using many fluorescent or quencher dye to label an oilgonucleotide, in which VIC is a suitable fluorescent dye for labeling oligonucleotide probe at the 5' end.(Claims 18 and 29).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and combine methods taught by Michinori et al., Kawai et al. and Lee et al. using the probe disclosed by Michinori selectively labeled with a fluorescent dye taught by Kawai et al. or Lee et al. absence unexpected result. Hence the claimed invention as a whole is *prima facie* obvious absence unexpected results.

Art Unit: 1648

Conclusion

The primers of SEQ ID NO: 4 and SEQ ID NO: 5 are free of art rejection; however, they are not allowable because they depend on the rejected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li

BAOQUN LI, MD
PATENT EXAMINER

BACQ
PATENT